REMARKS

The outstanding Official Action imposes a restriction requirement predicated upon the theory that the claims of the present application embody two distinct and independent inventions. The Official Action indicates that the first of these is denoted as Group I, encompassing Claims 1 to 10, drawn to a compound, classified in Class 546, subclass 119. The second of the two distinct and independent inventions, denoted as Group II, includes Claims 11 to 16, drawn to a composition and its method of use, classified in Class 514, subclass 303.

Groups I and II are deemed distinct and independent insofar as they are related as a product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used in a materially different process of using that product. MPEP §806.05(h).

The Official Action argues that, under both criteria, the claims of Groups I and II are distinct and independent. Specifically the Official Action avers that the product of Group I can be utilized in multiple uses. Moreover, the process for using the product as claimed can be practiced with another materially different product. In support of this allegation the Official Action emphasizes another compound for treating Alzheimer's disease.

Applicants, although electing Group I for prosecution on the merits in this application, traverse this restriction requirement.

Applicants submit that there is only one known use for the product described in Claims 1 to 10. That use, as set forth in Claim 11, is as an inhibitor of MAP kinases, preferably p38 kinase. As such, the sole use of the compound of Claims 1 to 10, constituting

Group I, is the treatment of MAP kinases mediated diseases in a mammal. Since, under MPEP§806.05(h), the sole utility of a product can be claimed in an application claiming the product, the inclusion of all the claims of the present application is appropriate.

It is emphasized that although a plurality of diseases are recited in Claims 13 and 14 as being amenable to treatment with the product of the claims of Group I, all of these diseases are MAP kinases mediated diseases. As such, the treatment of all these diseases represent the same utility.

The second basis for imposition of the instant restriction requirement is the alleged ability to practice the claimed process utilizing a materially different product. As illustration of this fact, the Official Action advances the use of Aricept in the treatment of Alzheimer's disease.

As stated above, the process of the claims of Group II is directed to the treatment of an MAP kinases mediated disease in a mammal. The Official Action does not establish that Aricept, for example, can be utilized in the treatment of any other MAP kinases mediated disease other than Alzheimer's disease. Thus, again, under MPEP§806.05(h), all the claims currently in this application are not subject to a restriction requirement.

For the above discussed reasons applicants submit that the restriction requirement of record is misplaced insofar as basis for distinctiveness, set forth at MPEP §806.05(h), does not apply to the claims of the present application.

The above remarks, which establish that the Official Action assertion of distinctiveness between the two sets of claims is not met, is buttressed by a second basis for removal of the provisional restriction requirement of record. That is, the statute, 35 C.F.R. §112, in its first sentence states:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. (Emphasis added)

Pursuant to this statutory dictate, the implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct. 37 C.F.R. §§1.141 - 1.142. Without both independence and distinctiveness, a restriction requirement is not authorized.

In the present application the two sets of claims, which the Official Action has grouped as separate inventions, are not independent of each other so as to justify a restriction requirement. The claims of Group I, Claims 1-10, are drawn to a product. These claims cannot be considered "independent" of the claims of Group II, Claims 11-16, drawn to compositions containing the product and methods of using the product. Rather, these two sets of claims are interrelated and interdependent.

The interdependence of the two allegedly independent sets of claims, set forth in the Official Action, is confirmed -- indeed it is mandated -- by virtue of the fact that the descriptive requirements of 35 C.F.R. §112 compel disclosure of all aspects of the two allegedly distinct and independent inventions of the present application. An application claiming a product must, of necessity, also describe its utility. That utility is defined by the composition and method claims, Claims 10-16, allegedly distinct and independent of product Claims 1-10, which product is utilized in the method and composition of Claims 10-16. Consequently, it is clear that all aspects of the present invention, including the product of Group I and the composition and method of the claims of Group II, are necessarily interdependent, not independent of each other. Thus, the above remarks provide yet further

support for the proposition that the requirement for restriction in the present application is misplaced.

Applicants note that the instant restriction is supported by reference to different classes and subclasses of the Patent and Trademark Office classification system in which the two groups of claims are classified. The inference that the classification of claims support a restriction requirement is submitted to be improper.

Reliance on a supposed classification of groups of claims does not establish independence and distinctiveness. The classification system has no statutory recognition with regard to whether inventions are independent and distinct. The sole purpose of the classification system is as an aid in identifying and searching for patents directed to the same general inventive entity.

The classification system is also an unreliable basis for requiring restriction between claims to various aspects of applicants' unitary invention because the Patent and Trademark Office classification system exhibits considerable overlap of technical definitions. In particular, the definition of classes and subclasses in the classification system does not prevent rejection of claims found in patent references classified in other classes or subclasses.

Furthermore, the classification system is a poor basis for restriction between related aspects of an invention insofar as classification definitions change over time. Thus, a classification that may have seemed to support restriction at a given time can change, thereby casting a shadow over the propriety of a restriction requirement later during the term of patents issued from parent and divisional applications. Indeed, classifications change in response to consideration of administrative convenience, often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have

nothing to do with whether the subject matter of patents assigned to different classifications are "independent and distinct," as those terms are used in 35 C.F.R.§121, which fact proves that basing restriction requirements on the classification system is improper.

The outstanding Official Action, imposing the above-discussed provisional restriction requirement, also relies on the recital of applicable sections of the Manual of Patent Examining Procedure (MPEP). Reference to the MPEP does not establish compliance with the narrow statutory authorization for a restriction requirement. The MPEP simply states the policy of the Patent and Trademark Office without the force of law. As such, the MPEP is not authority for expanding or altering a statutory grant of authority. This point is made by no lesser an authority than the Commissioner of Patents and Trademarks who has stated:

> The PTO can proscribe requirements in the MPEP provided these requirements are not inconsistent with the statute, the rules or the case law of the PTO's reviewing court. In re Fressola, 22 USPQ2d 1832 (Comm'r. PTO 1992)

It is emphasized that the restriction requirement of record is not mandatory and is indeed contrary to the public interest. Courts have recognized that it is in the public interest to permit an applicant to claim all aspects of an invention in a single application, as applicants have done herein. The CCPA has observed:

> We believe that the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe, in a manner required by 35 U.S.C. §112, all aspects as to what they regard as their invention, regardless of the number of statutory classes involved. In re Kuehl, 456 F.2d 658, 666, 117 USPQ 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed description supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application directed to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase in official fees and the resultant potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose of promoting and encouraging the progress of science and the useful arts.

It is vital that restriction requirements issue with only the proper statutory authorization because patents issuing on divisional applications, which are filed to prosecute claims that are held to be distinct and independent, can be vulnerable to legal challenge predicated upon the allegation of double patenting.

The third sentence of 35 U.S.C. §121, which states that a patent issuing on a patent application "shall not be used as a reference" against the divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same invention double patenting. Studiengellschaft Kohle mvP v. Northern Petrochemical Co., 784 F.2d 351, 355, 228 USPQ 837, 840 (Fed. Cir. 1986).

The same Court in Gerber Garment Technologies Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 USPQ2d 1436 (Fed. Cir. 1990) held that § 121 does not insulate a patentee from an allegation of "obviousness-type" double patenting and, in fact, the invalidation, on double patenting grounds, of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a Terminal Disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on a divisional application.

Although applicants have met the requirement that they elect the claims of one of the alleged inventions for prosecution on the merits, i.e. Group I, applicants submit that the above remarks establish the unitary nature of the claims of the present application which have been made subject to restriction. Reconsideration and removal of the provisional restriction requirement of record is thus deemed appropriate. Such action is respectfully urged.

Respectfully submitted,

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